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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,554	02/04/2006	Jeroen Alphons Tonnaer	2003-793US	2808
67706	7590	03/30/2010		
ORGANON USA, INC. c/o MERCK 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033			EXAMINER KIM, JENNIFER M	
			ART UNIT 1628	PAPER NUMBER
			NOTIFICATION DATE 03/30/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/560,554	TONNAER, JEROEN ALPHONS	
	<b>Examiner</b>	<b>Art Unit</b>	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

The amendment filed December 15, 2009 have been received and entered into the application.

### **Response to Arguments**

Applicant's arguments filed December 15, 2009 have been fully considered but they are not persuasive. Applicant essentially argues that neither the '476 patent nor the '831 patent offer any information addressing weight gain in treating patients with antipsychotic medications and there is simply no connection between the property discovered by the inventors, that weight gain is substantially non-existent in patients treated with asenapine and the cited articles. This is not persuasive because instant claims are drawn to a method for the treatment of schizophrenia in a patient which is either overweight or has a propensity to be overweight comprising administering asenapine wherein the term over weight is a patient having BMI in excess of about 25. It is noted that asenapine having antipsychotic effect and as being useful in the treatment of schizophrenia in sublingual route of administration is well known in the art in view of Delbressine et al. It is noted that schizophrenic patients being comorbid with obesity is high compared to general population as taught by Aronne who also defines the term "overweight" as the same definition employed in Applicant's claim 1. In this

Art Unit: 1628

case, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Org 5222 (asenapine) to schizophrenic patients comorbid with obesity defined as having BMI greater than or equal to 25 because Delbressine et al. teach that asenapine is useful for the treatment of schizophrenia and because obesity is highly comorbid with overweight condition having BMI greater than or equal to 25. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the term "overweight" is used a quotation mark which renders the claim indefinite because it is unclear whether the limitations within the quotation mark is a part of the claimed invention. It is suggested to delete the quotation mark.

The limitation of "a propensity to be overweight" is indefinite because it is not clear how one would determine whether the person "has a propensity to be overweight" without preexisting traits and medical conditions. One of ordinary skill in the art would

Art Unit: 1628

not be able to ascertain how to determine one having the propensity to be overweight from others not having the propensity.

Remaining claims are rejected to the extent that they depend from claim 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-12 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delbressine et al. (U.S. Patent No. 5,763,476) of record.

Art Unit: 1628

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Delbressine et al. do not expressly teach the kit and the composition accompany with a label.

However, it would have been prima facie obvious to one of ordinary skill in the art to include instructions such as label to how to administer to contents of the medicament, Org 5222 for that purpose. The instructions would differ from those recited in Applicants claims only in the wording of the instruction. Because the printed matter in the instructions has not functional relation with the composition on which it appears, it does not distinguish Applicant's claimed invention over that of Delbressine et al. *See In re Gulack*, 70 F.2d1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

Claims 1- 6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delbressine et al. (U.S.Patent No. 5,763,476) of record in view of Aronne (2001) and further in view of Alexander-Bridges et al. (U.S.Patent No. 5,496,831).

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Art Unit: 1628

Delbressine et al. do not teach that the schizophrenic patients disclosed by Delbressine et al. is overweight or has a propensity to be overweight with the term “overweight” defined as having BMI in excess about 25, the cause of the weight gain, the protection against weight increase and cause of the weight increase due to risk factors and overweight defined limits set forth in claims 4 and 5.

Aronne teaches that the rate of patients with schizophrenia comorbid with obesity is higher compared to the general population (abstract). **Aronne teaches the term “overweight” is defined as having a body mass index (BMI) of  $\geq 25$**  (page 13 left-hand column first full paragraph).

Alexander-Bridges et al. teach that obesity can be measured by determining the body mass index (BMI) which is the ratio of the weight (kg) to the square of the height (m) of the subject. The treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28. (column 5, lines 55-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Org 5222 (also known as asenapine maleate) to schizophrenic patients comorbid with obesity having a body mass index (BMI) of  $\geq 25$ . One would have been motivated to make such a modification because in general, the rate of a patient with schizophrenia comorbid with obesity that is known to be defined as a patient having a BMI of  $\geq 25$  as taught by Aronne and because Delbressine et al. teach that asenapine is useful for the treatment of schizophrenia in general. One would make such a modification in order to achieve a beneficial effect of asenapine in treatment of schizophrenia inclusive of those comorbid with obesity with the patient

Art Unit: 1628

having a body mass of  $\geq 25$ . There is a reasonable expectation of success in treatment of schizophrenia in a patient with overweight problems like obesity because the effectiveness of asenapine in treatment of schizophrenia would be retained regardless of their weight.

With regard to the definition of overweight set forth in claims 4 and 5, such are obvious requirement because Alexander-Bridges et al. teach that obesity can be measured by determining the body mass index (BMI) which is the ratio of the weight (kg) to the square of the height (m) of the subject. The treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28 as well known and encompasses Applicants definition of overweight set forth in claims 4 and 5.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the



Art Unit: 1628

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1628

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/  
Primary Examiner, Art Unit 1617

Jmk  
March 16, 2010

Application/Control Number: 10/560,554

Page 10

Art Unit: 1628